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REMARKS

This is in response to the Office Action dated June 23, 2006. Claims 20-24, 26, 27, and 30-37 are pending in the application. The Examiner rejected claims 20, 23, 24, 26, 27, and 30-33. Claims 21, 22 and 34 are objected to. Claims 20, 22, 26, and 34 have been amended. Support for the amendments can be found throughout the specification, and on at least page 7, lines 2-5, and page 8, lines 18-19 and 21-23. New claims 36 and 37 have been added. Support for claim 36 can be found throughout the specification and on at least page 21, lines 3-7. Support for claim 37 can be found throughout the specification and the drawings. No new matter has been added. Reconsideration and allowance of the claims is requested.

Claims 20, 23, 24, 26, 27, and 30-33 are rejected under 35 U.S.C. §103(a) as being unpatentable over Ross (5,089,015) in view of Hart et al (5,827,298). The Examiner states that Ross discloses a method for attaching a stentless heart valve comprising inserting fasteners (sutures) through the prosthesis into an aortic wall, but does not disclose the fastener having a head and a barbed tip. The Examiner also states that Hart teaches the use of a fastener having a head and a barbed tip, and that it would be obvious to combine the teaching of a fastener with a head and tip, as taught by Hart, to a method as per Ross. Applicant traverses the rejection.

Claim 20 has been amended to include the method of providing a fastener having a head and a sharp tip, and inserting the tip of the fastener through the prosthesis and through an aortic wall or root or a pulmonary artery wall. The method provides an efficient and easy to use fastening system for implantation of a heart valve prosthesis, and attachment to the aortic wall or root or pulmonary artery wall.. Using the fasteners, a physician can reduce the time to implant the prosthesis and the complexity of the implantation procedure. The fastening system is particularly useful in the implantation of aortic heart valve prostheses with flexible leaflets formed from tissue or polymer since the fasteners secure the commissure supports and scallops of the stentless valve to the aortic wall. (Page 7, lines 16-24, page 8, lines 24-27). The fasteners provide improved methods of attaching the heart valve prosthesis to the aortic wall., circumventing the

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need for extensive suturing and/or other devices, thus reducing cross clamp time (Page 10, lines 5-8).

The combination of Ross and Hart does not teach or suggest a fastener having a sharp tip that is inserted through the prosthesis and through an aortic wall or root or pulmonary artery. Ross discloses a method for attaching a stentless heart valve comprising inserting fasteners (sutures) through the prosthesis into an aortic root.

Hart appears to disclose a surgical fastener 5 with a distal end surface 20 having a blunt configuration, devoid of a cutting edge and devoid of a penetration point. The distal end surface 30 and proximal end surface 35 have substantially rounded configurations (col. 5, lines 21-24). An installation tool 75 comprises an inserter 80, inserter 80 including a carrier portion 83 which terminates in a sharp point 100. (Col. 6, lines 32-36). The inserter's carrier portion is adapted to carry surgical fastener 5 for deployment. (Col. 6, lines 39-40). The surgical fastener's distal end surface 30 sits completely within the inserter of the installation tool, withdrawn from the installation tool's sharp point 100, for deployment of the fastener (Col. 6, lines 63-65). Further, surgical fastener 5 is sized so that distal end surface 30 is completely buried within the receiving tissue once deployed. This prevents and insulates the distal end surface 30 of the surgical fastener 5 from engaging, and possibly interfering with, any bodily structures which may lie of the far side of the receiving tissue. (Col. 8, lines 19-30). It is the installation tool's sharp point 100, and not the fastener's distal end surface 30, that opens a way in the tissue. (Col. 8, lines 42-47).

Thus, Hart requires additional tools, procedures and time for implantation of fastener 5. Fastener 5 must be loaded into tool 75. Then installation tool 75 is required to cut the tissue with sharp point 100 so that fastener 5 can be installed. Fastener 5 itself does not penetrate the tissue, but rather follows through the cut from tool 75. Further, the distal end surface 30 of fastener 5 is buried within the tissue, and does not extend through to the far side. Installation tool 75 is removed once fastener 5 is implanted.

This is different than the Applicant's efficient, easy and direct method of implanting the fasteners to securely attach the prosthesis to the aortic wall or root or the pulmonary artery, where the fastener goes through the prosthesis and the aortic wall or root or pulmonary artery.

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This is done without all the extra time consuming steps required in Hart, thereby requiring less cross clamp time for the patient.

Since neither Ross nor Hart teach or suggest a fastener having a sharp tip that is inserted through the prosthesis and through an aortic wall or root or pulmonary artery, the combined teaching of Ross and Hart do not render Applicant's claimed invention prima facie obvious.

Applicant respectfully requests withdrawal of the rejection of claims 20, 23, 24, 26, 27, and 30-33 as being unpatentable over Ross in view of Hart.

In view of the foregoing, it is submitted that the application is in condition for allowance. The Examiner is requested to contact the undersigned representative if the Examiner believes it would be useful to advance prosecution.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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